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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,618	02/15/2002	Alexander J. Feigl	AFEI:002US 10006443	2880

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/077,618

Applicant(s)

FEIGL, ALEXANDER J.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on April 2, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 31-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 31-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on February 15, 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-11 and 31-41 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,190,396 to Whitin et al. Regarding Claim 1, and with reference to Figure 9, Whitin discloses a device including a body (20). Body (20) has a lumen (80) extending from a first lumen opening on the lateral side of the tube to a second lumen opening on the proximal end of the body. The lumen is adapted to receive a needle (70) and a suture [Column 9, lines 30-34]. The suture (inside and outside of the lumen) is visible in Figure 9.

Whitin's body (20) also has a first needle guide channel (80), which extends from a first needle guide channel opening on the lateral side of the tube to a second needle guide channel opening on the proximal end of the body. Examiner emphasized that Whitin discloses multiple lumens/channels, each having a separate proximal opening as is apparent from the cross sectional view of Figure 9.

Whitin's configuration is just as capable of performing the intended use as Applicant's invention. Whitin does not disclose such an intended use, but the user

could arrange the needle and suture in the configuration mentioned by Applicant and pull the suture, as intended by the Applicant.

2. Regarding Claims 2, 8, 9, 32, 38, and 39, each of Whitin's needle guide channels is shaped like an arc [apparent from Figure 9].
3. Regarding Claims 3-5 and 33-35, Whitin's device (10) has a handle coupled to body (20). The handle is especially well shown in Figures 1 and 2, and takes the form of a handle with a trigger, as in a gun. This handle is coupled to the body (20) through the various mechanisms of the device, as obvious in Figure 1. These mechanisms can be referred to as connector pieces. For example, one of the connector pieces are push rods (156), which must be bendable, because they "traverse the curved channel 80" [Column 9, lines 35-41].
4. Regarding Claims 6 and 36, Whitin's body is tapered, towards the distal end, as shown in Figure 9.
5. Regarding Claims 7 and 37, Whitin discloses multiple (eight, specifically) additional needle guide channels, each extending from its own first needle guide channel opening formed in the body (20) to its own second needle guide channel opening formed in the body. In Figure 9, although only one needle guide channel and one lumen are shown, this is because this view is a cross sectional view. Whitin discloses that either the pusher with push rods (156) as shown in Figure 12 or the pusher of Figure 11 may be used to push the needles/sutures through the needle guide channels of Figure 9 [Column 9, lines 32-41]. *This implies that there are as many channels to receive the needles/pushers as there are needles/pushers.*

Art Unit: 3731

6. Regarding Claims 10, 11, 40, and 41, because the pushers appear to be equidistant and arranged circumferentially [see Fig. 12], the needle guide channels (80) necessarily will also be equidistant and arranged circumferentially.
7. Regarding Claim 31, Whitin's body (20) has a first needle guide channel (80), which extends from a *first needle guide channel opening* on the lateral side of the tube to a second needle guide channel opening on the proximal end of the body. Thus, Whitin has anticipated a claim to a body with only one needle guide channel.
8. Further regarding Claims 31 and 37, Whitlin's apparatus is *capable of performing such an intended use*. As shown in Attachment #1, were one to back load the needle into the position as shown and pull on the suture forward (direction #1), then the needle will advance out of the body backwards (direction #2). Although Whitlin does not specifically disclose this use of his device, his device is capable of such a use. His device is certainly "*configured*" in such a way to allow this use of his invention.

### *Conclusion*

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from

the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Response to Arguments***

10. First of all, Examiner recognizes the cancellation of Claims 12-30 and 42-63.

Applicant's arguments filed April 2, 2004 have been fully considered but they are not persuasive. Figure 9 of U.S. Patent No. 6,190,396 B1 to Whitin et al. shows component 20 of the prior art suturing machine. Applicant recognizes (page 7, lines 12-15) that if one were to disassemble Whitin's suturing machine one would be able to backload a needle into one of the channels 80. Applicant contends that this component 20 is not a medical device. However, Examiner disagrees. The title of Whitin's invention is "Device and Methods for deploying and organizing sutures for anastomotic and other attachments." It is meant for use in connecting body ducts such as blood vessels [see Abstract]. Were a surgeon to disassemble the device on the operating table in a surgery room, he or she would certainly be able to use component 20 for guiding needles *in a medical procedure*. Applicant's use of case law does not change the Examiner's mind. The apparatus is not going through a metamorphosis, but merely being disassembled. One could disassemble a scalpel, separating the handle from the blade, and use the naked blade for a surgical procedure. Similarly, one could disassemble Whitin's medical device and use component 20 for the claimed use of the Applicant.

Art Unit: 3731

Further, Examiner contends that the claimed intended use (claim 1) can be performed using the machine *even in its fully assembled state* (as shown in Figure 1). Applicant does not positively recite a needle. A needle (not shown) could be back loaded into the distal end of lumen 80 and advanced out of the first needle guide channel by pulling on the suture loaded in another one of the lumens 80 [see Fig. 9].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

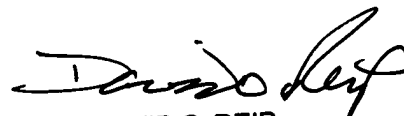
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BCP

June 1, 2004

DAVID O. REIP  
PRIMARY EXAMINER

ACTING SPE